REMARKS

Claims 1-6 and 8-13 were pending in the instant application. By this amendment, Claims 1 and 2 have been amended to present the rejected claims in form for allowance and Claims 14-26 have been added. In particular, Claim 1 has been amended to replace "treatment" with "protection of an excitable tissue." Support for the amendment is found at page 13, lines 16-31. Claim 2 has been amended to clarify that according to certain aspects of the invention the mammal has a neurodegenerative disease. Support for the amendment is found at page 5, lines 20-22.

Claims 14-21 have been added to claim certain embodiments of the invention related treating or protecting against injury or damage to neural tissue in a mammal. Support for the new claims is found at page 11, line 31 through page 12, line 5; page 14, lines 5-18; page 7, lines 26-30; page 34, lines 1-5; page 5, lines 20-22; abstract lines 6 and 7; page 25, line 1 through page 26, line 18; page 21, line 30 through page 22, line 4; page 13, lines 29 and 30; page 24, lines 5 and 6; and page 6, lines 16 and 17.

Claims 22-25 have been added to claim certain embodiments of the invention related to specific forms of treatment. Support for Claims 22-25 is found at page 6, lines 1 and 2; page 14, lines 3-14 and 21-27; page 29, lines 14-17; page 31, lines 1, 2, and 23-27; page 30, lines 4-12; page 32, lines 9-13 and 34-36; page 33, lines 27-33; and page 34, lines 1-6. Claim 26 has been added to claim certain embodiments of the invention related to specific neurodegenerative conditions. Support for Claim 26 is found at page 5, lines 30-35. As such, no new matter has been added.

Therefore, Claims 1-6 and 8-26 will be pending upon entry of the instant amendment.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF ENABLEMENT SHOULD BE WITHDRAWN

Claims 1-6 and 8-13 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enabling support in the specification. While the Examiner states that the specification

is enabling for a "method for protection of an excitable tissue comprising administering a non-toxic amount of EPO peripherally to a mammal suffering from a neurodegrenerative condition," the Examiner indicates it does not provide enablement for a method for the treatment of such neurodegenerative conditions, because such neurodegenerative conditions would encompass disease such as Alzheimer's and Parkinsons. (Advisory Action dated March 8, 2004, at ¶ 5). The Examiner has indicated, however, that the specification is enabling for "methods of improving cognitive function, improving memory, decreasing tissue necrosis in the brain and heart due to trauma, decreasing tissue necrosis in the brain due to hypoxia, decreasing neuronal injury due to excitotoxicity and delaying onset of encephalomyelitis in a mammal" (page 5 of the Office Action dated August 26, 2002).

In order to address the Examiner's concerns regarding the scope of enablement of the claimed methods, Claim 1 has been amended to recite a method for protecting excitable tissue. In addition, with respect to enablement of the scope of "neurodegenerative conditions," new Claim 14 has been added to replace "neurodegenerative condition" (of Claim 1) with "injury or damage to neural tissue," which is the underlying factor in neurodegenerative conditions encompassed by the instant invention. The specification clearly teaches administration of EPO to treat or protect excitable tissue from injury or damage (see page 11, line 31 through page 12, line 4; example 3 at page 31, line 5 through page 32, line 15; example, 4 at page 32, line 16 through page 33, line 14; example 5 at page 33, lines 15-34, and example 7 at page 34, line 21 through page 35, line 9). The Declaration of Michael Brines, submitted February 26, 2003, also demonstrates successfully treating or protecting against injury or damage to neural tissue in mammals in accordance with the teachings of the specification.

Thus, the teachings of the specification and the working examples provide adequate enabling support for the full scope of the claim, as amended, and undue experimentation

would not be required by one skilled in the art to administer EPO to successfully treat or protect against injury or damage to neural tissue in a mammal.

In view of the foregoing reasoning and amendment, applicants submit that the rejection for lack of enablement under 35 U.S.C. §112, first paragraph, should be withdrawn.

CONCLUSION

Entry of the foregoing remarks and amendment into the record of the above-identified application is respectfully requested. Applicants estimate that the remarks and amendment made herein now place the pending claims in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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